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RECIPIENT	COMPANY	FAX NO.	PHONE NO.
Director Group Art Unit 1600	USPTO	703 872-9306	

COMMENTS:

Re: Petition to Director to Review Restriction Requirement Pursuant to 37 C.F.R. § 1.144

Please deliver attached Petition to:

Director of Group Art Unit 1600

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PAGE 1/7 * RCVD AT 7/19/2004 4:56:21 PM [Eastern Daylight Time] * SVR:USPTO-EFAXF-1/7 * DNIS:8729306 * CSID:01116173109000 * DURATION (mm-ss):02-14

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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JUL 19 2004

In re the application of: Kimberly A. Gillis et al.

Application No.: 09/996,529

Confirmation No. 3553

Filed: November 28, 2001

For: Expression Analysis of Inhibitor of
Differentiation Nucleic Acids and Polypeptides
Useful In the Diagnosis and Treatment of Prostate
Cancer

Attorney Docket No.: 102729-14

Group Art Unit: 1642

Examiner: Davis, Minh Tam B.

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19 July 2004	By:
Date of Signature and Transmission	Thomas J. Engellemer Reg. No. 28,711

Director of Group Art Unit 1600
P.O. Box 1450
Alexandria, VA 22313-1450PETITION TO DIRECTOR TO REVIEW RESTRICTION REQUIREMENTPURSUANT TO 37 C.F.R. § 1.144

Dear Sir:

Pursuant to 37 C.F.R. § 1.144, Applicants respectfully request that the Director review and reconsider the Restriction Requirement mailed from the Patent Office on February 17, 2004 and made final in the Office Action mailed May 19, 2004.

Application No.: 09/996,529

In the Office Action mailed from the Patent Office on February 17, 2004, the Examiner divided the 35 pending claims into 34 patentably distinct groups requiring election of one of the following 34 groups:

Groups 1-3: Claims 1-7, 11-16; Class 435, subclass 6.

Method detecting prostate cancer by measuring mRNA level or ID1 or ID3 marker or combination

Groups 4-6: Claims 1, 3-10; Class 435, subclass 7.1.

Method of detecting prostate cancer by measuring protein level of ID1 or ID3 marker or combination

Groups 7-9: Claims 17-21; Class 435, subclass 6.

Method of monitoring progression of prostate cancer by measuring mRNA level of ID1 or ID3 marker or combination.

Groups 10-12: Claims 17, 19-21; Class 435, subclass 7.1.

Method of monitoring progression of prostate cancer by measuring protein level of ID1 or ID3 marker or combination.

Groups 13-14: Claims 22, 35; Class 435, subclass 6.

Method of assessing efficacy of treating prostate cancer by measuring mRNA level of ID1 or ID3 marker.

Groups 15-16: Claims 22, 35; Class 435, subclass 7.1.

Method of assessing efficacy of treating prostate cancer by measuring protein level of ID1 or ID3 marker.

Groups 17-18: Claim 23: Class 435, subclass 6.

Method of assessing the potential of a test compound to trigger prostate cancer by measuring mRNA level of ID1 or ID3 marker.

Groups 19-20: Claim 23: Class 435, subclass 7.1.

Method of assessing the potential of a test compound to trigger prostate cancer by measuring protein level of ID1 or ID3 marker.

Groups 21-22: Claim 24: Class 514, subclass 2.

Method for treating prostate cancer by administering ID1 or ID3 protein.

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Groups 23-24: Claim 25: Class 514, subclass 44.

Method for treating prostate cancer by expressing ID1 or ID3 protein by an expression vector.

Groups 25-26: Claims 26-27, 29: Class 435, subclass 6.

Method for identifying a compound useful for treating prostate cancer by measuring the mRNA level of ID1 or ID3 markers in the presence or absence of the compound.

Groups 27-28: Claims 26, 28-29: Class 435, subclass 7.1.

Method for identifying a compound useful for treating prostate cancer by measuring the protein level of ID1 or ID3 markers in the presence or absence of the compound.

Groups 29-30: Claims 30-31: Class 435, subclass 7.1.

Method for identifying a compound useful for treating prostate cancer by measuring the activity of ID1 or ID3 markers in the presence or absence of the compound.

Groups 31-32: Claims 32-33: Class 514, subclass 44.

Method for treating prostate cancer comprising administering a compound which increases the mRNA level of ID1 or ID3.

Groups 33-34: Claims 32, 34: Class 514, subclass 44.

Method for treating prostate cancer by administering a compound which increases the protein level of ID1 or ID3.

For the purpose of being responsive to the Restriction Requirement mailed from the Patent Office on February 17, 2004, Applicants elected Group 3, claims 1-7 and 11-16 (drawn to methods of detecting prostate cancer by measuring mRNA level of a combination of the ID1 and ID3 markers) with traverse. However, Applicants respectfully believe that the restriction requirement, as issued, is improper and respectfully request reconsideration.

Applicants' invention is directed to using Inhibitor of Differentiation (ID) markers, *e.g.*, ID-1 and ID-3, as genetic markers for the detection, diagnosis, treatment and prognosis of prostate disorders. The invention provides methods and screening assays for the detection and

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diagnosis of prostate cancer, as well as for testing for compounds that effect the expression levels of ID proteins in prostate cancer.

Applicants respectfully request that the Director reconsider the restriction requirement in light of the arguments presented below. Specifically, Applicants request that both markers, ID1 and ID3, of the present invention be examined in this application because examination of *two sequences* does not present an undue burden on the Examiner.

In addition, Applicants believe that the invention should not be restricted to either nucleic acids or proteins since the claims are directed to measuring the expression level of ID markers which can be monitored by *either* measuring the nucleic acids associated with ID (e.g., RNA, or DNA), or the ID protein levels.

Alternatively, if the Director considers nucleic acids and proteins to be separate and distinct inventions, the Applicants respectfully requests that the Director amend the grouping such that all claims directed to either nucleic acids or proteins are examined together.

Examination of Two Sequences Does Not Constitute a Serious Burden

Applicants disagree with the restrictions imposed by the Examiner in that they split up the two markers, ID1 and ID3, of the claimed invention. The screening methods described by the invention encompass *both* markers, individually and in combination. Forcing an election between the two markers, ID1 and ID3, is totally unnecessary. According to MPEP 803.04:

“the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction.” (Emphasis added.)

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Applicants believe that examining *two sequences* would not present a serious burden to the Examiner since it is only one-fifth of the number determined to be a "reasonable number for examination purposes." Furthermore, Applicants contend that the two sequences, ID1 and ID3, do not fall into the "exceptional" category that would necessitate that the reasonable number of sequences be less than ten. In addition, Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks, clarified the PTO's policy for examination of patent applications that claim large numbers of nucleotide sequences in his Notice entitled "Examination of Patent Applications Containing Nucleotide Sequences" (October 17, 1996, 1192 OG 68). The Notice elaborated on the PTO's policy of *not* restricting combination of nucleotide sequences:

"Applications claiming only a combination of nucleotide sequences ... will generally *not* be subject to a restriction requirement. The presence of one novel and nonobvious sequence within the combination will render the entire combination allowable. The combination will be searched until one nucleotide sequence is found to be allowable." (Emphasis added.)

Applicants also stress the PTO's statement that allowing Applicants to claim more than one "independent and distinct nucleotide sequences in a single application will promote efficient, cost-effective examination" See *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996). Thus, Applicants urge that the groups be amended such that the both markers ID1 and ID3 are examined in this application.

Nucleic Acids And Proteins Encoded Thereby are Not Distinct Inventions

Reconsideration of the restriction requirement is also requested because nucleic acids *encoding for* the ID markers and the ID marker proteins *encoded by* the nucleic acids are not distinct inventions since the nucleic acids and proteins claimed are integrally related. The invention is drawn to measuring the expression levels of ID proteins (e.g., ID1 and/or ID3) associated with prostate cancer. The expression level can be monitored by *either* measuring the nucleic acids associated with ID (e.g., RNA, or DNA), or the ID protein levels. Forcing an election between nucleic acids and proteins would require that the Applicants amend the claims

so that they fit into the groups, as requested by the Examiner in the first Office Action of the merits mailed May 19, 2004. Accordingly, the Director is requested to amend the restriction requirement such that both mRNA and protein of the ID1 and ID3 are examined together in this application.

Approved _____ Date _____